

**THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

This document relates to:
All Actions

No. 1:19-md-2875-RBK

Hon. Robert B. Kugler
Special Master Thomas I. Vanaskie

**PLAINTIFFS' MEMORANDUM OF LAW
IN SUPPORT OF RULE 37 SANCTIONS AGAINST ZHP**

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PRELIMINARY STATEMENT

This Court has ordered Defendant ZHP to produce important discovery, including the deposition of its Chief Executive Officer, General Manager, and Founder, Baohua Chen. ZHP has violated those Orders, brazenly advising the Court and Plaintiffs that it would not comply and blaming the Chinese government for precluding it from doing so. Plaintiffs cannot be left without the ordered discovery, and without any remedy, as this would cede control of the course of this litigation to the Chinese government. Thus, this motion for definitive Rule 37 sanctions is the only reasonable pathway forward.

The Court has ordered the following discovery that ZHP has refused to provide: (1) the deposition of Baohua Chen, who served as the linchpin of its development, manufacture, sale, and recall of contaminated valsartan, (2) the production of the custodial file of Baohua Chen's chief of staff, Xiaofang (Maggie) Kong, (3) the production of an internal ZHP report investigating the [REDACTED] of irbesartan [REDACTED], which was discussed in the July 27, 2017 email [REDACTED]
[REDACTED]
[REDACTED], (4) all documents referencing "TC-201729," the code for the irbesartan [REDACTED] investigation, and (5) the production of all documents related to the batch testing for nitrosamines referenced in PRINSTON0075797. ZHP has refused to comply with these Orders, claiming that it is blocked from doing so under Chinese law.

The Court has provided on-point guidance to the Parties in a recent decision, addressing similar arguments concerning Chinese "state secrets." In that decision, the Court explicitly stated that Chinese "blocking statutes" will not excuse ZHP's compliance with the Court's Orders under the Federal Rules of Civil Procedure. The Court clearly warned ZHP that it would issue sanctions, including "findings of fact adverse to a party that has failed to comply with the order for

production, even if that party has made a good faith effort to secure permission from the foreign authorities to make the information available and that effort has been unsuccessful.”

Plaintiffs now request that this Court strike and suppress ZHP and its subsidiaries’ Answer and Defenses, deem the allegations in Plaintiffs’ Master Complaints admitted with respect to ZHP and its subsidiaries for all purposes, and preclude ZHP and its subsidiaries from defending Plaintiffs’ claims. Any lesser sanction will permit ZHP to evade Court Orders without any significant consequence, and will incentivize and enable further obstruction of this litigation.

PROCEDURAL HISTORY

This motion follows a year of difficult litigation in an effort by Plaintiffs to establish their claims in this MDL. On December 31, 2020, the Court ruled that Baohua Chen was a proper deponent, and granted Plaintiffs “leave to file a motion requesting production of Mr. Chen’s custodial file” and ZHP leave to file a motion for a protective order to preclude the deposition based on a “sufficient deposition record.” ([ECF 704](#)). The Parties scheduled Mr. Chen’s deposition for May 31, 2021.

On April 27, 2021, based on the record established during the depositions of numerous ZHP witnesses, Plaintiffs requested that the Court order the production of Mr. Chen’s custodial file. ([ECF 1189](#)). After allowing ZHP to brief its opposition in full, the Court agreed with Plaintiffs and ordered ZHP to produce Mr. Chen’s custodial file. ([ECF 1315](#)).

On May 17, 2021, ZHP filed a motion for a protective order to preclude the deposition of Mr. Chen. ([ECF 1247](#)). On June 22, 2021, Special Master Vanaskie denied this motion. ([ECF 1330](#)). Three days later, ZHP informed Special Master Vanaskie that it was considering a challenge to his denial “that would have to be done I believe by July 13th.” ([6/25/2021 Tr. 6:23:23-25](#)). Special Master Vanaskie consequently postponed the scheduling of Mr. Chen’s deposition to

allow that motion to be filed and ruled upon. (*Id.* at 11:1-8). ZHP filed its objection on July 13, 2021. ([ECF 1386](#)). The Court ultimately denied ZHP's motion. ([ECF 1453](#), [1472](#), [1475](#)).

On October 26, 2021, ZHP first disclosed that “on October 25, 2021, Duane Morris was informed that, due to his governmental responsibilities, the Chinese government has verbally denied Mr. Chen’s request for a permit to travel to Macao to be deposed in this action.” ([ECF 1673](#), p. 1-2). At the October 27, 2021 case management conference, ZHP told the Court that “since Monday evening, I do not have an update on this.” ([10/27/2021 Tr. 4:8-9](#)). Special Master Vanaskie told ZHP to “report to your counterparts in China that the Court has ordered that the deposition be taken by December 15th so that they understand that there is a deadline in place and hopefully this deadline can be accommodated.” (*Id.* at 6:17-20). On November 9, 2021, ZHP informed Plaintiffs and the Court that it did not have anything new to report. ([ECF 1739](#), p. 2). The next day, ZHP confirmed this at a status conference: “[W]e don’t have an update, but we hope to and intend to communicate with plaintiffs on the issue when we have more information.” ([11/10/2021 Tr. 10:25-11:2](#)). On November 22, 2021, ZHP provided its first update in its letter to the Court regarding the next case management conference:

Due to his roles at various levels of Chinese official organizations, which we previously identified for the Court, *see* ECF No. [1244](#) at 9, Mr. Chen was required to obtain the permission of the Communist Party Committee within ZHP to travel outside of mainland China to be deposed in this action, and he was also required to obtain similar permission from the Taizhou Public Security Bureau, Exit-Entry Administration and the Taizhou Federation of Industry and Commerce. We understand that the Communist Party Committee within ZHP granted Mr. Chen’s request on June 10, 2021. However, both the Taizhou Public Security Bureau, Exit-Entry Administration and the Taizhou Federation of Industry and Commerce denied Mr. Chen’s travel request on October 27, 2021, and, as counsel for ZHP we learned last week that, after further discussions between ZHP and the PRC government, those denials were confirmed to ZHP on November 11, 2021.

([ECF 1766](#), p. 3-4). Thus, ZHP had known of the November 11 confirmation of the denials but inexplicably waited until November 22 to notify Plaintiffs.” ([12/01/2021 Tr. 5:1-6:8](#)). Special Master Vanaskie concluded, “I do believe that you [(Plaintiffs)] should be able to move for sanctions.” (*Id.* at 8:6).

During this time period, Plaintiffs also sought the production of (1) the custodial file of Baohua Chen’s chief of staff, Xiaofang (Maggie) Kong, (2) the report investigating the [REDACTED] of irbesartan [REDACTED], discussed in the July 27, 2017 email by [REDACTED]
[REDACTED]
[REDACTED], (3) all documents referencing “TC-201729,” the code for this investigation, and (4) all documents relating to the batch testing for nitrosamines referenced in PRINSTON0075797. Plaintiffs first raised these requests with the Court on April 27, 2021. ([ECF 1189](#), p. 15-17, 21-22, 24, 26). On May 11, 2021, the Court ordered the production of (2), (3), and (4). ([ECF 1233](#)). After hearing additional oral argument, the Court also ordered the production of (1), Maggie Kong’s custodial file:

I’m going to direct that Ms. Kong be added as a custodian, for her custodial file to be reviewed. If there then is a proportionality objection to be asserted based upon what volume of documents we’re looking at and some evidentiary basis for the assertion that the overwhelming majority of those documents would be privileged, then I’d be willing to say nothing needs to be produced, that on proportionality grounds, it doesn’t need to be produced.

([5/12/2021 Tr. 32:15-33:1](#)). During the June 16, 2021 status conference, ZHP asked the Court to extend its deadline for producing Mr. Chen’s and Ms. Kong’s custodial files to July 12, 2021. ([6/16/2021 Tr. 14:19-15-24](#)). ZHP never made a proffer as to a proportionality issue. And with regard to (2) through (4), ZHP’s partial production was inadequate. As a result, on July 23, 2021, Plaintiffs filed a motion to compel ZHP’s compliance with [ECF 1233](#) as well as the Court’s May 12, 2021 order. ([ECF 1405](#)). On August 13, 2021, ZHP opposed the motion. ([ECF 1485](#)). During

oral argument, after the Court ordered ZHP to again produce the custodial file of Xiaofang (Maggie) Kong, ZHP informed the Court that it would not comply with the Order due to China's new Data Security Law. ([9/10/2021 Tr. 59:10-61:20](#); [ECF 1550](#), p. 20-21). Not surprisingly, Special Master Vanaskie was "disappointed" that ZHP waited until after he issued an order to produce the custodial file to raise this issue. ([9/10/2021 Tr. 62:15](#)). The Court issued its formal Order granting Plaintiffs' motion with respect to (1) through (4) on November 12, 2021. ([ECF 1753](#)). The Order required ZHP to produce (1), (2), and (3) by November 22, 2021, and "[i]f the parties are unable to resolve [the] dispute [regarding (4)], the ZHP Parties shall present, no later than December 7, 2021, competent evidence of the anticipated cost of producing the testing records sought by Plaintiffs, along with an affidavit addressing other, less costly options for production of the testing results." (*Id.*) ZHP never presented such evidence regarding (4) to Court.

On November 22, 2021, ZHP confirmed that it did not intend to produce (1) through (4). ([ECF 1766](#), p. 4-6). ZHP reaffirmed its position at the December 1, 2021 case management conference. ([12/01/2021 Tr. 14:13-15:1](#)).

**BAOHUA CHEN IS THE LINCHPIN OF
THE ZHP ORGANIZATION AND ITS CONTAMINATED VALSARTAN**

Plaintiffs have established Baohua Chen's central role in the ZHP organization as well as the development, manufacture, sale, and recall of its contaminated valsartan. Baohua Chen is the CEO of ZHP and Shanghai Syncores. (ZHP00076700, Ex. 1;¹ ZHP00076708, Ex. 2). Syncores is ZHP's wholly-owned research entity that in 2011 developed the zinc chloride manufacturing process that resulted in contamination of valsartan with NDMA. An organization chart states that "[a]ll the VP or directors are reported to Baohua Cheng [d]irectly," and shows that Mr. Chen is

¹ Unless otherwise noted, all exhibits are attached to the Certification of Adam M. Slater in Support of Plaintiffs' Motion for Rule 37 Sanctions Against ZHP.

the common denominator between ZHP, Shanghai Syncores, Prinbury, Huahai US, Princeton, and Solco. (ZHP00076709, Ex. 2).

Mr. Chen is not just a figurehead, he has direct technical knowledge and training. According to ZHP's Drug Master File (DMF) for valsartan, which was filed with the FDA, **Mr. Chen is a** [REDACTED]

[REDACTED]
[REDACTED]

[REDACTED] (ZHP01662344 (emphasis added), Ex. 3; *see also* ZHP01633850, Ex. 4; ZHP01458548, Ex. 5).² **Mr. Chen has a Master of Science in Chemical Engineering.** (ZHP00004937 (emphasis added), Ex. 6). ZHP's valsartan DMF also states, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] (ZHP01662359 (emphasis added), Ex. 3). As already mentioned, all vice presidents or directors report to Mr. Chen directly; thus, **as the "General Manager," he effectively and independently leads all of ZHP's departments and is responsible for coordinating and synthesizing their disparate activities.** He managed 3,800 employees as of May 2014. (ZHP00004937, Ex. 6).

² A DMF is the regulatory filing that an API manufacturer files with the FDA in order to allow finished dose manufacturers to incorporate its API into its applications for FDA approval. *See* FDA, *Drug Master Files (DMFs)*, <https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs>. This Court should give significant weight to the claims made in such a filing.

During FDA inspections, Mr. Chen told the FDA that he “has the ultimate authority at the firm and takes **full responsibility for the company’s operations.**” (PRINSTON00083647 (emphasis added), Ex. 7).³ Mr. Chen participated in at least seven FDA inspections during the relevant time period, in August 2013, May 2014, March 2015, November 2016, June 2017, January 2018, and June 2019. At the August 2013 inspection, the Vice General Manager of Quality Assurance said that he reported directly to Mr. Chen. (PRINSTON00083002, Ex. 8). After that inspection, Mr. Chen “promised to correct/evaluate all discussion items and to expand the corrections to any related issues.” (PRINSTON00083010, Ex. 8). The March 2015 inspection reports identified Baohua Chen as the “most responsible person.” (PRINSTON00083028, 31, Ex. 9). The May 2014, November 2016, and January 2018 inspection reports state that all FDA correspondence should be addressed to Mr. Chen. (PRINSTON00074128, Ex. 10; PRINSTON00081551, Ex. 11; PRINSTON00081574, Ex. 12).

[REDACTED]

[REDACTED]

(ZHP0000222, an English translation, Ex. 13). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (ZHP02579748 (emphasis added), Ex. 14). Z [REDACTED]

[REDACTED]

[REDACTED] (SOLCO00012089, Ex. 15 (stating that [REDACTED]

[REDACTED] (emphasis

³ The document clearly states that “[a]t the close-out meeting, the firm was represented by Baohua Chen.” (PRINSTON00083644, Ex. 7). ZHP’s repeated efforts to paint Mr. Chen as a know-nothing figurehead are as cynical as they are belied by the documents.

added)); ⁴ SOLCO00189499, Ex. 16 [REDACTED]

[REDACTED]

(sic)); SOLCO00025179, Ex. 17; SOLCO00033301, Ex. 18; SOLCO00181380, Ex. 19; SOLCO00180393, Ex. 20). **Demonstrating the practical significance of the strategy spearheaded by Mr. Chen, ZHP told the FDA that it changed to the contaminating zinc chloride manufacturing process in order to lower the cost of its valsartan and dominate the world market as a result.** (PRINSTON00162373, Ex. 21).

In addition, based on the evidence to date, **it is highly unlikely that Mr. Chen did not know about the NDMA contamination of the valsartan, and the root cause,** [REDACTED] [REDACTED] **as this decision ensured that ZHP's revenue stream would not be disrupted.** [REDACTED]

[REDACTED]

Mr. Chen also led ZHP's recall of Valsartan. ZHP's "Protocol of Valsartan API Recall (Foreign grade)" lists Mr. Chen as the first member of the "Recall Group," and that group does not include Jun Du, who is the CEO of all three of ZHP's U.S. subsidiaries, which are all based in New Jersey. (ZHP00494048, Ex. 22). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



(ZHP01423197 (emphasis added) Ex. 23).



(ZHP00292153, Ex. 24).



(ZHP00292149, Ex. 24).



(ZHP02666849,

Ex. 25).



(*Id.*)

Shortly after the disclosure of the nitrosamine contamination, Mr. Chen even flew to Beijing one “weekend to talk with Chinese FDA officials so that they keep their Chinese market alive” and tried “speaking with government officials as well to see if there is any chance of official

talks between China and the US.” (TEVA-MDL2875-00611842, Ex. 26). His involvement was not distant and supervisory—he was engaged and a leader of ZHP’s work on this matter.

Mr. Chen also handled customer complaints regarding the recall. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (ZHP01224767 (also stating in an earlier email in the chain that

[REDACTED]

[REDACTED]

[REDACTED]) (emphasis added), Ex. 27). Mr. Chen

was also the main point of contact for another defendant in this case after the recall – Teva. (See

TEVA-MDL2875-00662718, Ex. 28; TEVA-MDL2875-00370081, Ex. 29; ZHP01761094, Ex.

30). [REDACTED]

[REDACTED]. (ZHP00667853,

Ex. 31). [REDACTED] (See PRINSTON00468994, Ex.

32; ZHP02471924, Ex. 33; ZHP02490581, Ex. 34).

As already explained, all departments report directly to Mr. Chen, ZHP’s CEO and General Manager. Jun Du, the head of all of ZHP’s U.S. subsidiaries, admitted that his title as ZHP’s Executive Vice President was temporary and for the convenience of Mr. Chen. (5/27/2021 Tr. Jun Du Dep. 34:5-8 (stating, “Those were merely interim assignments. **Whenever Baohua Chen as the general manager was unavailable, someone was needed for the coordination.**” (emphasis added)) (Ex. 39)).

ZHP 30(b)(6) witness Min Li testified that after the June 2018 disclosure of the contamination to the FDA and other regulatory authorities, which only occurred after Novartis discovered the contamination and forced ZHP to disclose it, [REDACTED]

[REDACTED]

[REDACTED] (4/22/2021 Tr. of Min Li Dep. 581:14-582:5 (emphasis added), Ex. 40). Demonstrating the need to depose Mr. Chen, Min Li provided a string of evasive testimony about Baohua Chen's involvement:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(4/22/2021 Tr. of Min Li Dep. 581:9-612:13 (emphasis added), Ex. 40).

ZHP 30 (b)(6) witness, Jucai Ge, its Director of API Quality Assurance at the Chuannan Site ([ECF 1386-1, p. 15](#)), also illustrated the need for Mr. Chen's deposition:

Q. During the meetings, what did Mr. Chen say to you?

A. I can't describe to you the gist of his statement to you. I cannot recall the original wording of his and I cannot recall which meeting he made such statements in.

* * *

Q. Please give me your best estimate as to how many meetings you participated in with Mr. Chen regarding NDMA?

A. I don't remember exactly how many times.

Q. Give me your best estimate.

A. My estimate would not be that accurate.

Is that okay?

Q. Yes.

A. Well, I would just provide a rough estimate.

Q. Yes, please provide -- provide it right now.

A. For all kinds of meetings where NDMA was mentioned, I believe it's five meetings also.

Q. Okay. Who attended these roughly five meetings with Mr. Chen regarding NDMA?

A. I don't recall who specifically those attendees were, but typically I would attend for the meetings I was there and a QP would be there, people from QC would be there. So it's pretty much people from those department, although the attendees would vary. They would be there to follow up with the progress and sometimes vice president Min Li -- spelled as M-i-n, last name L-i -- would also be there, but I don't recall specific attendees.

Q. Did you take notes during these approximately five meetings with Mr. Chen?

A. There was nothing to take notes for. **I never take notes.** All he said was, Hey, hurry up or do it according to the GMP requirement. It's nothing worth taking notes for.

* * *

Is it part of your job description to know what Mr. Chen does from -- on a day-to-day basis?

A. **It -- it is not.**

(4/30/2021 Tr. of Jucai Ge Dep. 368:11-371:21, Ex. 41). Yet another example of Mr. Chen's active role, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (ZHP02385482, Ex. 35).

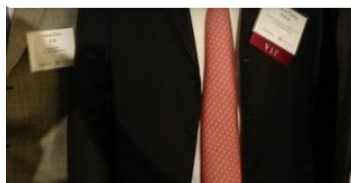
Hai Wang, the Vice President of Prinston and President of Solco, testified that [REDACTED]

[REDACTED]

[REDACTED] (3/11/2021 Tr. of Hai Wang Dep. 542:18-43:5, Ex. 43). The Facebook page of PrinJohnson, an intermediate holding company between Huahai US and Prinston, which in turn owns ZHP's U.S. distribution subsidiary Solco, focuses on Mr. Chen's involvement in these operations:



Baohua Chen Chairman of PrinJohnson



([Photo from PrinJohnson's Facebook Page](#), Ex. 42).



([Photo from PrinJohnson's Facebook Page](#), Ex. 42). Moreover, Plaintiffs have cited numerous documents above establishing that Hai Wang relied on Mr. Chen to determine the price of Valsartan and balance that price with his target for ZHP's market share. Once again, all major decisions point to Mr. Chen, whether they are communications with the FDA, the product development and recall, or the pricing of ZHP's valsartan.

Baohua Chen was involved at every point in the process, and has direct knowledge from all corners of the company that Plaintiffs cannot learn or confirm from other sources. Plaintiffs' inability to account for key matters Mr. Chen was at the heart of, and confirm what he knew and when, including but not limited to the inadequate risk assessments of the TEA and zinc chloride processes, the decision to develop the contaminating zinc chloride process, the decision to hide the contamination in order to maximize corporate profits, and the grudging disclosure only when Novartis forced ZHP to do so, among other subjects, significantly prejudices the Plaintiffs.

**ZHP'S SUPPLEMENTAL PRODUCTION
ENCOMPASSES KEY DOCUMENTS AND INFORMATION**

Xiaofang (Maggie) Kong is the chief of staff for Baohua Chen, and her custodial file has significant importance in part because of the obviously inadequate production of Mr. Chen's custodial file. ZHP claims to have produced Baohua Chen's custodial file, but when it was first produced, it only contained 326 documents, the earliest of which was dated January 24, 2018. (Ex. 36). ZHP subsequently amended its production to add Baohua Chen as a duplicate custodian on an additional 305 documents, none of which predated the earliest document from the original production (January 24, 2018). Of course, most of the key events predate that time frame. Given the inadequate production for Mr. Chen, Xiaofang (Maggie) Kong's custodial file is quite important.

The second category of documentary discovery is equally crucial to Plaintiffs' case. It concerns the irbesartan investigation discussed in [REDACTED] July 27, 2017 email [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(ZHP 296, Ex. 37).⁵ For context, Dr. Lin was [REDACTED]

[REDACTED]

[REDACTED]. (ZHP 432 (stating:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], Ex. 38).

[REDACTED]

[REDACTED]

[REDACTED] (4/20/2021 Tr. of Min Li Dep. 125:19-126:6, Ex. 48).

In part, the email reads:

[REDACTED]

⁵ Despite his critical knowledge regarding the existence and root cause of the NDMA contamination of ZHP's valsartan – almost one year before disclosed by ZHP – no litigation hold was directed to Dr. Lin, raising significant issues. (Declaration of Pei Zhang Verifying ZHP's Distribution of Its Litigation Holds, Ex. 47).

(*Id.* at 127:20-128:7). [REDACTED]

[REDACTED]

[REDACTED] (*Id.* at 128:11-138:17). [REDACTED]

[REDACTED] (*Id.* at 138:13:18-139:17). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. (*Id.* at 136:5-10). T [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*Id.* at 128:11-139:17 (emphasis added)). [REDACTED]

[REDACTED] (*Id.* at 140:9-17).

ZHP produced a single copy of this investigation report after the Court ordered it to produce all copies, and ZHP has not produced a native version of this document, which was clearly created using a computer, and the metadata does not include real dates (only “12/31/9999 11:59 PM EST”).

Nevertheless, the content of the email is revealing:

- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (ZHP02710348, an English translation (emphasis added), followed by the original document, Ex. 49).

- [REDACTED]
[REDACTED]

[REDACTED]

(ZHP02710350 (emphasis added), Ex. 49).

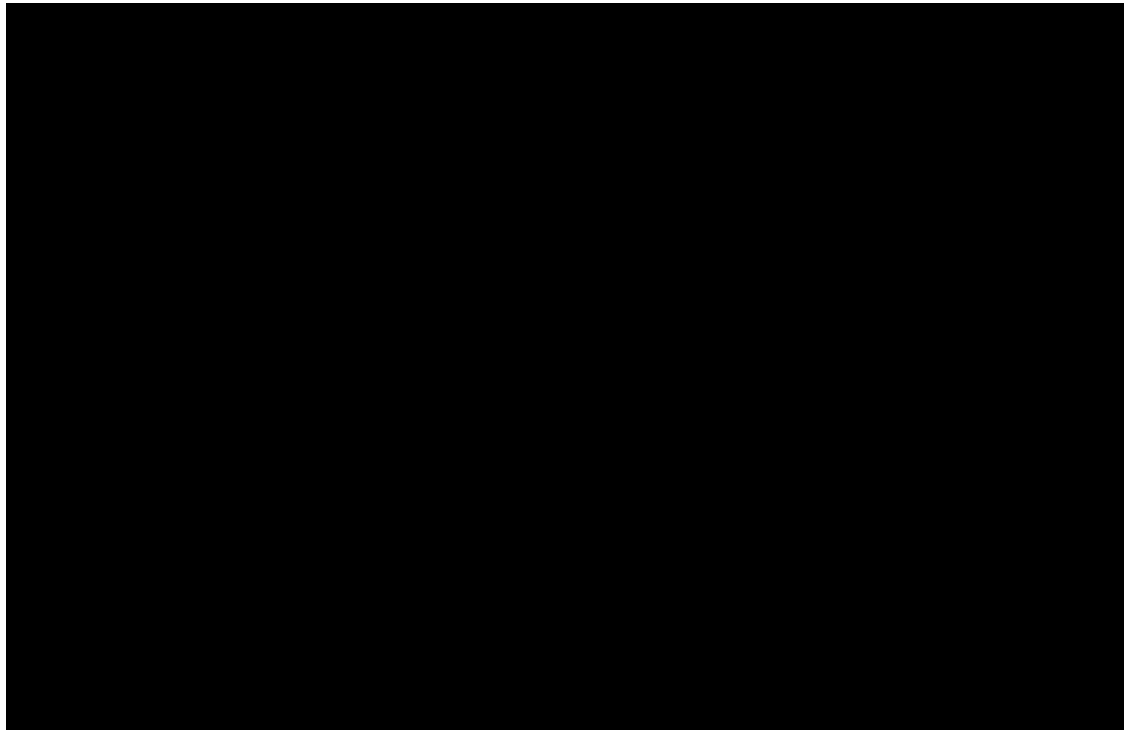
- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (ZHP02710351 (emphasis added), Ex. 49).

- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (ZHP02710351 (emphasis added), Ex. 49).

Plaintiffs have a right to understand how and when this report developed and whether it was revised further [REDACTED]. Moreover, any drafts could shed further light on the July 27, 2017 email's reference to [REDACTED]

[REDACTED]

Next, PRINSTON0075797 references test results for 7,000 valsartan API batches and summarizes them as follows:



(PRINSTON0075838, Ex. 50). In response to these requests, ZHP repeatedly directed Plaintiffs to Production ZHP017. ([6/25/2021 Tr. 33:25-34:7](#)). However, that production only includes USDMF grade valsartan. (*Id.*) The above chart summarizes results for [REDACTED] [REDACTED]. Plaintiffs need these additional test results to confirm the full scope of contamination levels documented by ZHP's testing. In addition, this will allow Plaintiffs to confirm the levels in the valsartan sold in other markets where epidemiologic studies have been and potentially will be conducted using the public health services or other sources of data available in those countries. (Pottegård, Kristensen, Ernst, Johansen, Quartarolo, & Hallas, *Use of N-nitrosodimethylamine (NDMA) contaminated valsartan products and risk of cancer: Danish nationwide cohort study*, B.M.J. 12, 362 (Sept. 2018), Ex. 51; Gomm, Röthlein, Schüssel, Brückner, Schröder, Heß, Frötschl, Broich, & Haenisch, *N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer: A Longitudinal Cohort Study Based on German Health Insurance Data*, DEUTSCHES AERZTEBLATT INTERNATIONAL 118, 357-62 (2021), Ex. 52).

The Court's November 25, 2019 Macro Discovery Order required the production of these records from the beginning of this case. ([ECF 303](#) (ordering that "Plaintiffs are entitled to discovery regarding any test that could identify the presence of nitrosamine contamination. Also, testing and results regarding other carcinogens, general toxic impurities, or residual solvents in the Valsartan API and Valsartan is relevant"). The Court made clear the importance of this information when it issued its Macro Discovery Order:

Parties may obtain discovery of non-privileged information relevant to any party's claim or defense that is proportional to the needs of the case.

Although this MDL is or is likely to be massive in scope in terms of the number of potential claimants and the amount in controversy, the Court will not disregard the necessity of proportionality when it comes to deciding the discovery plaintiffs will be permitted to take.

The fact that this MDL is likely to involve thousands of potential claimants and disputes over hundreds of millions of dollars is no reason to approve duplicative, unnecessary, cumulative, and unduly burdensome discovery.

On the other hand, when it evaluates the proportionality of plaintiffs' discovery requests, the Court cannot ignore the fact that hundreds of millions of dollars, perhaps even a billion dollars, may be in dispute.

The Court also cannot ignore the fact that Valsartan was and is a very popular high blood pressure medication perhaps taken by millions of people and that serious health concerns have been raised, although not yet proven, about the present and future health effects resulting from taking contaminated Valsartan.

It is beyond dispute that the public has a keen interest in the results of this litigation, and the issues in dispute are undoubtedly important to the public health and welfare. In addition, it is just as apparent that plaintiffs do not have access to the relevant information they need to prove their case, and that key information, such as when and how the Valsartan contamination occurred is within defendants' exclusive possession. These are relevant factors Rule 26 directs this Court to consider in its proportionality analysis.

([11/20/2019 Tr. of Oral Opinion Deciding the Parties' "Macro" Issues, 6:15 7:22](#)). The Court then concluded, "Clearly, plaintiffs are entitled to obtain discovery regarding any test that could identify

the presence of nitrosamine contamination, such as NMBA and NDEA.” (*Id.* at 21:23-25). It is unconscionable that ZHP failed to produce these documents with its original production, which was due in late 2020. Its defiance of multiple Court Orders cements the need for the requested sanctions.

LEGAL ARGUMENT

I.

RULE 37 SANCTIONS ARE REQUIRED TO REMEDIATE ZHP’S FAILURE TO COMPLY WITH THE COURT’S DISCOVERY ORDERS

There is no sanction short of definitive Rule 37 sanctions that will adequately match the prejudice from ZHP’s refusal to comply with Court Orders compelling discovery. And though the case law describes a heavy burden, that burden cannot be applied as an insurmountable or nearly so barrier to the imposition of real consequences in the circumstances here. The sanction must meet the conduct. A strong, decisive Order is the only just remedy for this obstruction, and the only means to avoid setting a dangerous precedent that would allow further interference and encourage foreign governments such as China to deprive United States citizens of the justice promised by our laws.

This Court explained the consequences for invoking Chinese “blocking statutes” in its recent Opinion:

In looking at the likely effect these PRC laws do and will have on the U.S. market, I find this a most important consideration. Even though between a” legal rock and hard place”, PRC defendants cannot enter the U.S. market expecting a possible shield from unfavorable discovery by PRC blocking statutes. As one judge's decision has implied, if you don't like the rules, then stop doing business in the U.S.

Any expectation that a PRC law will successfully shield discovery in a U.S. litigation needs a tempering of realism. That is, PRC defendants must know from the outset they risk serious consequences if and when they fail to obey a U.S. court's order to compel discovery. These consequences arise from the clearly

enumerated authority under Rule 37, which U.S. courts wield as needed.

An example of a court imposing such a tempering realism is found *In re Activision Blizzard, Inc.*, []86 A.3d 531, 552 (De. Ch. Ct. 2014). There, the court required French defendants to make a good faith effort to obtain promptly the assistance of the appropriate French authority in deciding the disclosable nature of documents at issue. This good faith effort is similar to what I see ZHP has done. However, the Activision court's patience was not infinite in that the French defendants were given a deadline by which the blocked French documents had to be produced, with or without the French authority assistance. The court stated:

“If [document] production has not been authorized [by the French authority] by March 31, 2014, when substantial completion of document production is due, then the [French] Defendants shall produce on that date the documents called for by the plaintiff's discovery requests or face the prospect of sanctions in this court. In considering sanctions, the court will be guided by the factors cited in Section 442 of the Restatement [Third of the Foreign Relations Law] and will take into account the recommendation in Section 442(2)(c) of the Restatement that the appropriate sanctions involve making ‘findings of fact adverse to a party that has failed to comply with the order for production, even if that party has made a good faith effort to secure permission from the foreign authorities to make the information available and that effort has been unsuccessful.’ Restatement § 442(2)(c).”

Importantly, the non-compliance of a Court Order risks the imposition of Rule 37 sanctions.

In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig., MDL No. 2875, 2021 WL 6010575, at *18-19 (D.N.J. Dec. 20, 2021) (emphasis added) (footnotes omitted) (Ex. 53) ([ECF 1825](#)). This

Court also pointed to the sanctions permitted under Rule 37(b)(2)(A):

(i) directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action, as the prevailing party claims;

(ii) prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence;

(iii) striking pleadings in whole or in part;

(iv) staying further proceedings until the order is obeyed;

(v) dismissing the action or proceeding in whole or in part;

(vi) rendering a default judgment against the disobedient party; or

(vii) treating as contempt of court the failure to obey any order except an order to submit to a physical or mental examination.

Id. at *18 n.45. The sanctions provided in Rule 37 are particularly appropriate here, and are the only means to remedy ZHP's violation of this Court's Orders.

In terms of the importance of the discovery, as demonstrated above, Baohua Chen is the linchpin of the ZHP organization, its manufacture of contaminated valsartan, the likely financially-motivated cover up of ZHP's knowledge that the contamination existed, and the subsequent recall, all of which amounts to Plaintiffs' case against ZHP. In affirming the Special Master's denial of ZHP's motion for a protective order from his deposition, this Court found:

-Mr. Chen is and has been closely involved in ZHP operations and in the decision-making to change the API solvent(s);

-These operational changes appear to have precipitated the contamination of ZHP's API; and

-Mr. Chen's was involved in responding to the FDA's recalls.

([ECF 1475](#)).

The custodial file of Mr. Chen’s chief of staff, Xiaofang (Maggie) Kong, is also crucial, as ZHP produced a grossly deficient custodial file for Mr. Chen. In ordering its production, the Court found that Ms. Kong’s custodial file constitutes a “significant source of discovery.” ([ECF 1753, p. 5](#)). ZHP is also withholding a native version of the report investigating the [REDACTED] of irbesartan [REDACTED], related to the July 27, 2017 email [REDACTED]
[REDACTED]
[REDACTED] “TC-201729,” the code for this investigation. These documents go to the heart of Plaintiffs’ case—the nitrosamine contamination of ZHP’s sartans. And finally, ZHP continues to withhold fundamental documents relating to the results of batch testing for thousands of batches of valsartan API referenced in PRINSTON0075797. This includes the NDMA and NDEA test results for the markets where crucial epidemiological studies have been conducted. As already explained, ZHP should have produced these test results in 2020 with its main discovery production under the Court’s Macro Discovery Order. Despite the Court’s subsequent May 11 and 12, 2021 orders to produce these documents and Plaintiffs’ July 23, 2021 motion to compel their production, ZHP waited until after the enactment of a blocking statute to notify Plaintiffs and the Court that it could no longer produce the documents under an interpretation of China’s Data Security Law that this Court has now rejected. *Valsartan*, 2021 WL 6010575, at *10 (holding: “That injunction is inapplicable to these documents or indeed to any information produced in response to an FRCP discovery request.”). The Court should also note that the National People’s Congress, of which Baohua Chen is a member, promulgated this law. ([ECF 1766-1, p. 52](#)).

Given the overwhelming importance of this discovery and the Court’s prior analysis of the *Aérospatiale-Wultz* balancing factors, this Court should follow its prior guidance and strike and suppress ZHP’s Answer and Defenses, and deem the allegations in Plaintiffs’ Amended Master

Complaints admitted with respect to ZHP and its subsidiaries for all purposes. *Valsartan*, 2021 WL 6010575, at *11-19. This relief is clearly well supported here. In a similar case, *Abiola v. Abubakar*, No. 02 C 6093, 2007 WL 2875493, at *20 (N.D. Ill. Sept. 28, 2007) (Ex 54), that court noted:

There is no question that given the order of the Nigerian court, Abubakar would face a significant sanction in that country were he to submit to a deposition. The Court has considered this, and it has also considered the national interest claimed by Nigeria when it sought and obtained the order barring Abubakar from appearing for a deposition. **But given all the circumstances, those factors do not outweigh the plaintiffs' need for his testimony, the severe prejudice they face if they are unable to obtain his testimony, and the interest of this country in allowing the plaintiffs to seek relief via the TVPA. By refusing to comply with this Court's order to appear for a deposition, Abubakar has subjected himself to the imposition of a significant sanction.**

Id. at *19 (emphasis added). As a result, the Court held that **“the appropriate sanction is to enter a[n] order, as permitted by Federal Rule of Civil Procedure 37(b)(2)(A), that the allegations in plaintiffs' second amended complaint relevant to Abubakar's liability are to be taken as established for the purposes of this suit.”** *Id.* at *20 (emphasis added); *see also* *Munoz v. China Expert Tech., Inc.*, No. No. 07 Civ. 10531, 2011 WL 5346323, at *1 (S.D.N.Y. Nov. 7, 2001) (ordering the production of discovery despite a Chinese “block statute,” and holding: **“If defendants do not act in accordance with the law and practices of the United States courts, sanctions may be appropriate, including the striking of pleadings and other appropriate sanctions.”**) (Ex 55).

Anticipating ZHP’s response, this Court has correctly held that the Hague Convention does not obviate its authority to order discovery under the Federal Rules of Civil Procedure and ZHP’s corresponding obligation to comply with those orders: “[T]he Hague Convention in no way deprives a District Court of jurisdiction to compel a foreign national party to produce evidence physically located within a Hague Convention signatory nation.” *Valsartan*, 2021 WL 6010575,

at *4 (citing *Aérospatiale v. U.S. Dist. Court for Southern Dist. of Iowa*, 482 U.S. 522, 539-40 (1987)). In fact, “[t]he parties agree that under Rule 30(b)(1), a witness may be noticed for a deposition to provide testimony on behalf of a corporation if the witness is an officer, director or managing agent of the corporation.” ([ECF 1061](#) (citing *In re: Benicar (Olmesartan) Products Liab. Litig.*, No. 15-2606 (RBK/JS), 2016 WL 581762, at *3 (D.N.J. Oct 4, 2016) (citing *Campbell v. Sedgwick Detert, Moran & Arnold*, No. 11-642 (ES/SCM), 2013 WL 1314429, at *12 (D.N.J. Mar. 28, 2013))).

Next, ZHP has blamed Plaintiffs for not seeking Mr. Chen’s deposition under the Hague Convention, as discussed above, an argument that bears no credibility. ([ECF 1766](#), p. 3). Plaintiffs note that **“in more than 30 years under the Consular Convention and 13 years under the Hague Convention, China has granted permission for a deposition on only one occasion.”** *Inventus Power v. Shenzhen Ace Battery*, --- F.R.D. ---, 2021 WL 4477940, at *11 (E.D. Ill. Sept. 30, 2021) (emphasis added); *see also Jacobs v. Floorco Enterprises, LLC*, No. 3:17-CV-90-RGJ-CHL, 2020 WL 1290607, at *15-16 (W.D. Ky. Mar. 18, 2020) (“attempting to take the deposition of Tu in China does not appear likely to succeed under the Hague Convention process”)) (Ex. 46). Moreover, ZHP cannot credibly claim that the Chinese government would grant such a deposition under the Hague Convention if Baohua Chen, who is a member of the Chinese Communist Party as well as the National People's Congress of the People's Republic of China, with a net worth of over a billion dollars, cannot obtain permission to leave the country for his deposition pursuant to this Court’s Order under the Federal Rules of Civil Procedure, an arrangement that is standard for the deposition of Chinese nationals in this case as well as every other case proceeding in the United States. (See Forbes, #2035 *Chen Baohua*, <https://tinyurl.com/2p88subx>, Ex. 44; [ECF 701](#), Ex. 1 (stating, **“Unless otherwise agreed, a Chinese national residing in mainland China will travel from mainland China to Hong Kong for the deposition, including for a deposition taken via**

videoconference.”). As shown above, Baohua Chen has obtained permission to travel to New Jersey on behalf of ZHP in the past; thus, the blocking action by China is nothing more than calculated obstruction of the United States justice system. Any effort by ZHP to turn this situation against the Plaintiffs should be rejected.

In addition, ZHP claims that China’s new Data Security Law (“DSL”), effective September 1, 2021, prevents it from complying with the Court’s May 11 and 12, 2021 orders requiring the production of (1) the custodial file of Baohua Chen’s chief of staff, Xiaofang (Maggie) Kong, (2) a report investigating the [REDACTED] of irbesartan [REDACTED], related to July 27, 2017

[REDACTED], (3) all documents referencing “TC-201729,” the code for this investigation, and (4) all documents relating to the batch testing for nitrosamines referenced in PRINSTON0075797. ([ECF 1233](#); [5/12/2021 Tr. 32:15-33:1](#); *see also* [ECF 1753](#)). ZHP relies on a declaration from Xueyu Yang, quoting Article 36 of the law and claiming that ZHP must consequently “obtain the government’s permission prior to producing any additional documents intended for use in this litigation.” ([ECF 1766](#), p. 5). This Court has rejected the soundness of Ms. Yang’s declaration. *Valsartan*, 2021 WL 6010575, at *3 (“With full respect for Ms. Yang’s credentials, the Court cannot evidence that her opinion is methodologically reliable.”). Even more important, this Court has explicitly rejected ZHP’s understanding of Article 36 of the DSL. *Id.* at *10 (holding: “That injunction is inapplicable to these documents or indeed to any information produced in response to an FRCP discovery request.”).

ZHP has had months to comply with this Court’s Orders, and the only reasonable alternative is to impose definitive sanctions. *See Valsartan*, 2021 WL 6010575, at *18-19 (holding, “Any expectation that a PRC law will successfully shield discovery in a U.S. litigation needs a tempering of realism.”).

CONCLUSION

For the foregoing reasons, it is respectfully requested that this Court strike and suppress ZHP and its subsidiaries' Answer and Defenses, deem the allegations in Plaintiffs' Amended Master Complaints admitted with respect to ZHP and its subsidiaries for all purposes, and preclude ZHP and its subsidiaries from defending Plaintiffs' claims.

Dated: December 30, 2021

Respectfully Submitted,

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